MHRA Board

MINUTES OF THE MEETING

15 July 2016

Present:

The Board

Professor Sir Michael Rawlins	Chairman of MHRA
Mr Martin Hindle	Deputy Chairman
Dr Ian Hudson	Chief Executive
Mr Peter Commins	Chief Operating Officer
Dr Barbara Bannister MBE	Non-Executive Director
Professor Dame Valerie Beral	Non- Executive Director
Mr Matthew Campbell-Hill	Non-Executive Director
Professor Bruce Campbell	Non-Executive Director
Mr Stephen Lightfoot	Non-Executive Director
Professor Sir Alex Markham	Non-Executive Director
Ms Deborah Oakley	Non-Executive Director

Others in attendance

MHRA executive and supporting officials

Mr Jonathan Mogford	Director of Policy
{Redacted: Section 40: Freedom Information Act (FOIA) – personal data}	deputising for the Director of Communications
Mr Richard Humphreys	Deputy Finance Director
Mr Gerald Heddell	Director of Inspection, Enforcement and Standards - item 5
{Redacted: Section 40 of FOIA}	Medicines Borderline Section Manager - item 5
{Redacted: Section 40 of FOIA}	Clinical Trials Unit Manager – item 6
{Redacted: Section 40 of FOIA}	Head of Corporate Affairs, NIBSC
{Redacted: Section 40 of FOIA}	Head of Science Strategy
Mr Aidan McIvor	Head of Directorate
{Redacted: Section 40 of FOIA}	Executive Assistant to the Chairman

Department of Health (DH) and Legal Services

Mrs Claire Armstrong	Deputy Director (Medicines, Pharmacy and Industry Division)
Mr Mark Wilson	DH Legal Services

Devolved Administrations

Wales: Mrs Janet Davis, Acting Deputy Director of Healthcare Quality Division

Item 1: Introductions and Announcements

1.1 Apologies were received Professor David Webb, Non-Executive Director; and Rachel Bosworth, Director of Communications.

1.2 Sir Michael welcomed everyone to the meeting, including Mrs Janet Davis from the Welsh Assembly Government, who is the first official from a Devolved Administration to attend an MHRA Board meeting as an observer.

Peter Commins, Chief Operating Officer,

1.3 As this was the last Board meeting that Peter Commins would attend before retiring in September, Sir Michael asked that the minutes record the Board's deep gratitude to Mr Commins for his past services. Sir Michael said that he and other members of the Board would express their gratitude to Mr Commins more fully on 12 September at a farewell dinner to mark Mr Commins' retirement.

1.4 Sir Michael announced that Richard Humphreys, Deputy Finance Director, will attend all future Board meetings until Peter Commins' successor is in post.

Item 2: Declarations of interest

2.1 None was declared.

Item 3: Minutes of the last meeting, 17 June 2016, and matters arising

3.1 Subject to a minor change, which the Board agreed, the draft minutes of the Board meeting of 17 June 2016 were endorsed. The change concerned the intention of the Audit and Risk Committee (ARAC) to meet again to consider a final report from the National Audit Office. Deborah Oakley, Chair of ARAC, reported that ARAC had reconvened on 1 July where, having considered a final report from the NAO, the ARAC recommended that the draft Annual Accounts could be signed by Dr Hudson, Chief Executive and Accounting Officer. The Board heard that the Annual Report and Accounts were now with the Comptroller and Auditor General and were expected to be laid before Parliament on 21 July.

Matters arising

3.2 The Board reviewed the actions list from previous meetings. During the review of the actions list, Dr Hudson reported that the Corporate Risk Register is being revised following the outcome of the EU Referendum.

DISCUSSION ITEMS

Item 4: EU Referendum - update

4.1 Jonathan Mogford presented a paper on how the Agency has responded to the outcome of the EU Referendum of 23 June; the paper also sought the Board's initial views on possible options for the Agency's in a post EU setting.

4.2 The Board heard that a cross-agency task force was set up on 24 June comprising senior officials from the Agency's eleven divisions. The task force has sought and received feedback from across the Agency on the risks and opportunities posed by the referendum outcome; the feedback will help inform the task force's thinking as further scoping work takes place and scenarios are mapped out. The Board was also updated on the Agency's messaging (external and internal), as well as the close liaison with the Department of Health, the Office of Life Sciences, and other key stakeholders, such as the trade associations.

4.3 Dr Hudson advised that the Agency's position is 'business will continue as normal at present whilst the UK considers the way forward following the referendum vote', with the Agency engaging proactively with staff and stakeholders to ensure there is no information vacuum on what is happening, etc.

4.4 Redacted: Section 35: Government policy in development.

4.5 Redacted: Section 35: Government policy in development. Sir Michael thanked Mr Mogford for the update and sought the Board's views. These centred on the following areas:

- *Opening remarks* – Sir Michael and the Board thought it was vital to engage quickly and proactively with industry, other key stakeholders and staff. The Board was assured by Dr Hudson and Mr Mogford that this is being done. Dr Hudson advised that within the past ten days he has had a number of meetings with UK trade association representatives, and has had discussions with counterparts from the European medicines network as well as the Executive Director of the EMA. The Board welcomed this assurance, for there was concern that uncertainty and an information vacuum could be corrosive.

- *Operational consequences/ Operational transformation & IT* – The Board thought that Brexit was bound to add to the workload of MHRA's staff. Dr Hudson acknowledged this additional workload recognising that work would need to be prioritised to ensure this post referendum work continued rapidly. The Board recommended that, in light of the EU Referendum outcome, the operational transformational /IT programmes should be stress-tested for various scenarios. This is to ensure that on-going costs of any IT-related expenditure are affordable.

- *Opportunities* – The Board advised that there would be many opportunities for the MHRA in a post-EU environment, especially as the MHRA has a well-deserved reputation for being much more nimble and efficient than many other agencies, e.g. clinical trials authorisations. These strengths should be built on.

- *Impact of multiple issues*– Whereas in January 2016, when the Board /CET had its last strategic away day, the Agency was facing a much more stable future, the situation has changed considerably with Brexit, the accommodation move as well as Operational Transformation, thus substantially increasing the risks and uncertainties facing the Agency.

- *Impact on Europe* – The Board thought that, depending on the type of relationship the UK will have the EU, the European medicines and medical devices' network will, to a varying degree, feel the absence of the UK, as the MHRA is a major participant in the European network.

- Redacted: Section 35: Government policy in development.

4.6 A further update will come to Board on 12 September. By then, the first stage of the task force's scoping work will have been completed.

Item 5: Judicial Appeal on Glucosamine containing products

5.1 Gerald Heddell introduced {name redacted – Section 40), who presented the paper. The Board heard that there is a longstanding and widespread availability of glucosamine containing products (GCP) sold as food supplements in the UK and, since 2008 a small

number of marketing authorisations (MA) have been issued for GCP for specific clinical indications. An MA holder has challenged the Agency's position regarding the legal status of the supplement products. This led to a Judicial Review in 2014, where the High Court upheld the Agency's position that only those GCP which make a medical claim should be regarded as medicines. The ruling was subsequently appealed and on 17 June the Court of Appeal ruled that MHRA must give further consideration to its approach regarding the classification of GCP.

5.2 {Name redacted – Section 40) explained the complex nature of the case and the read-across to other products, such as vitamin supplements. Dr Jones then outlined the judgement and options available to the Agency. There were seven points, each of which the CET considered in detail at its meeting on 12 July, which could be regarded to be grounds to seek an appeal to the Supreme Court.

5.3 {Name redacted – Section 40) went on to explain that on 12 July, the CET, having considered the case in great detail, decided that the current judgement should be appealed; and as the deadline for lodging an appeal was 14 July, an appeal was lodged in time. {Name redacted – Section 40) advised that even though an appeal had been lodged, it could subsequently be withdrawn.

5.4 Sir Michael thanked {Name redacted – Section 40) for the paper and then sought the Board's views. The Board asked if clarification could be sought from the High Court on parts of its judgement. Mark Wilson advised that that would not be possible. The Board advised that the implications of this case touched on other substances, such as caffeine, which is used in neonatal care and is used as food additive.

5.5 Sir Michael and the Board thanked {Name redacted – Section 40) for his report and endorsed the CET's decision to lodge an appeal. The Board considered that the expense was justified in the light of the difficulties which the current judgement, with its lack of clarity, could pose for the Agency. The Board also endorsed the CET's decision that work on 'a review of the GCP classification decision', which formed part of the Appeal Court judgment, should begin in parallel with an appeal to the Supreme Court.

Item 6: French phase 1 First-in-Human Clinical Trial

6.1 Redacted: Section 5: Commercial confidentiality

Item 7: A framework of Quality Assurance for Responsible Offices and Revalidation

7.1 {Name redacted: Article 40 – personal data} presented the Revalidation Annual Report – A Framework of Quality Assurance for Responsible Officers and Revalidation. The Revalidation Framework was introduced in 2014 in order to provide a quality assurance required to demonstrate that the Responsible Officer and Designated Body are discharging their respective statutory responsibilities.

7.2 The Board considered the following documents:

(i) The third Revalidation Annual Report covering the period April 2015 to March 2016 (Responsible Officers are required to present an annual report to their board or management team)

(ii) The Annual Organisation Audit (AOA) (end of year questionnaire submitted to NHS England /Department of Health)

(iii) A Statement of Compliance, which should be signed off by the Chairman before 30th September and submitted to the higher level responsible officer (the Chief Medical Officer).

7.3 The Board heard that the revalidation process for MHRA's clinical assessors in 2015/16 had gone well; this was borne out by the positive feedback about the appraisers in the recent external audit conducted by the MIAD (leaders for appraiser training). {Name redacted: Article 40 – personal data} concluded by reporting that Sir Alex Markham, NED, will succeed Professor Angus Mackay, as principal assessor for senior medics in the Agency.

7.4 The Board welcomed the assurance provided by the report that the Agency's approach is robust, comprehensive and thorough

STANDING ITEMS

Item 8: CEO's report

8.1 Dr Hudson presented the highlights from the CEO's monthly report. These centred on the following areas:

- *Operation Pangea IX* – An update was given on the work of the International Internet Week of Action, Operation Pangea IX, which took place from 31 May to 7 June. In total, 193 agencies from 103 countries participated in operation that had a particular focus on medical devices.

- *House of Commons Science and Technology Committee Inquiry into regenerative medicines* - an update was given on the Agency's response to the Parliamentary inquiry. The Agency's response set out the regulatory framework and highlighted the Agency's role in its development at EU level. The Parliamentary Committee is likely to take oral evidence in September.

- *Accommodation* - An update was given on the work of the Relocation Programme Board and its three project groups. The latter will consider 'needs and vision', 'move' 'acquire' and 'exit'.

- *GCP prosecution*– An update was given on the successful prosecution of a medical doctor in Northern Ireland following a long investigation into falsification of a clinical trial.

- *E-cigarettes* –. The Board also heard that Sir Michael Rawlins had met with Lord Prior of Brampton to brief the Minister on the Agency's work to implement the notification scheme for e-cigarettes.

Item 9: Finance and Procurement report

9.1 Mr Richard Humphreys gave the highlights for first two months of the financial year 2015/16. They were:

- MHRA (Regulator) operating income: year to date was £8.0m.
- NIBSC operating income: year to date was £0.7m.
- CPRD operating income: year to date was £0.3m.
- Total operating income for the Agency was £25.6m; £0.6m above budget.
- Total operating costs were £22.8m, which are £0.4m below budget.

- The Agency's bank balance at the end of May 2016 was £216.6m.
- Capital expenditure for the year to end of May 2016 was £0.6m.
- The number of full-time equivalents (FTE) in May 2016 was 1,222 employees.

9.2 As part of his report, Mr Humphreys gave an overview on the possible implications of the EU Referendum outcome on the Agency's income profile. At present, there were no signs of any perceptible changes, but that is likely to change in 2017. The Board heard that Schedule 8 (Income Risk Assessment) of the Financial Report had been prepared prior to the outcome of the EU Referendum; the next report will be revised to reflect the changed circumstances.

Item 10: Audit and Risk Assurance Annual Report

10.1 Deborah Oakley, Chair of the Audit and Risk Assurance Committee, presented the Audit and Risk Assurance Annual Report 2015/16, which was noted by the Board.

Item 11: Cyber and Information Security update for Non-Executive Directors (NEDs)

11.1 John Quinn a presented paper on cyber and information security, which was specifically prepared for NEDs. Similar online advice and training is available on Civil Service Learning's (CSL) website. The paper outlined the information and communications environment in which NEDs work. Mr Quinn explained the security classification system (official, secret, top secret) and the information structure for MHRA. The latter covered the roles and responsibilities of the Agency's Accounting Officer, Senior Information Risk Owner, and Information Asset Owners. John Quinn then outlined the broad areas of risk for the Agency: (i) people, (ii) processes and (iii) technology. The paper also covered the risks posed by working away from the office and provided a range of practical advice on 'dos and don'ts'.

11.2 The Board thanked Mr Quinn for the update, which they thought was timely and most informative. The NEDs said they are looking forward to the roll out of the new share point system, which NEDs will be able to access via new Board pads.

Item 12: Minutes of the Corporate Executive Team (CET) of 5 May 2016

12.1 The minutes of the CET meetings of 5 May 2016 were noted.

Item 13: Any Other Business (AOB):

13.1 The Board meeting dates for 2017, which were tabled, were noted.

13.2 One of the NEDs suggested that consideration be given to a meeting with the Department of Business, Energy and Industrial Strategy to explore opportunities for greater international collaboration/international trade.

Date of next Board meeting: 12 September 2016